PATENT 10/625,221

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

SCHLIEVERT ET AL.

Examiner:

UNKNOWN

Serial No.:

10/625,221

Group Art Unit:

1645

Filed:

JULY 22, 2003

Docket No.:

600.311USD1

Confirmation No.:

UNKNOWN

Customer No.:

23552

Title:

MUTANTS OF STREPTOCOCCAL TOXIN A AND METHOD OF USE

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 22, 2003.

Name: Sheryl A. Boerboom

# INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted within three months of the filing date of the above-identified application, which is not an application under 37 C.F.R. § 1.53(d). Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(d), a copy of each document or other information listed on the enclosed Form 1449 is not provided because it was previously cited by or submitted to the U.S. Patent and Trademark Office in parent application, U.S. Serial No. 08/973,391 filed on March 12, 1998.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a

reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C. P.O. Box 2903 Minneapolis, MN 55402-0903 (612) 332-5300

DATE: Oct 22, 2003

Mark T. Skoog Reg. No. 40,178

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PATENT TRADEMARK OFFICE

Date Mailed: October 22, 2003

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## INFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION

(Use several sheets if necessary)

## Docket Number: 600.311USD1

Application Number: 10/625,221

Applicant: SCHLIEVERT ET AL.

Filing Date: July 22, 2003

Group Art Unit: 1645

#### U.S. PATENT DOCUMENTS FILING DATE **SUBCLASS** CLASS NAME DOCUMENT NO. DATE **EXAMINER** IF APPROPRIATE INITIAL Kotzin et al. 08/09/1994 5,336,598 Kotzin et al. 03/29/1994 5,298,396 FOREIGN PATENT DOCUMENTS TRANSLATION **SUBCLASS CLASS** COUNTRY DATE DOCUMENT NO. NO YES 08/05/1993 **PCT** WO 93/14634 02/28/1985 PCT WO. A, 85 00832 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Acharya, K. et al., "Structural Basis of Superantigen Action Inferred from Crystal Structure of Toxic-Shock Syndrome Toxin-1", Nature 367:94-97 (1994). Aiyar, A. et al., "Modification of the Megaprimer Method of PCR Mutagenesis: Improved Amplification of the Final Product", BioTechniques Vol. 14, No. 3 (1993) pages 366-369. Altschyl, S. et al., "Optimal Sequence Alignment Using Affine Gap Costs", Bulletin of Math. Biol. 48:603-616 (1986). Anthony-Cahil, S. et al., "Site-specific mutagenesis with unnatural amino acids", Trends in Biochem. Sci. 14:400-403 (1989). Barsumian et al., "Nonspecific and Specific Immunological Mitogenicity by Group A Streptococcal Pyrogenic Exotoxins", Infection and Immunity 22:681-688 (1978). Belani, K. et al., "Association of exotoxin-producing Group A streptococci and severe disease in children, Pediatr. Infect. Dis. J. 10:351-354 (1991). Betley et al., "Staphylcoccal Enterotoxins, Toxic Shock Syndrome Toxin and Streptococcal Pyrogenic Exotoxins: A Comparative Study of their Molecuar Biology", Chem. Immun. 55:1-35 (1992). Birkhaug et al., "Studies in Scarlet Fever II: Studies on the Use of Convalescent Scarlet Fever Serum in Dochez Scarletino Antistreptococcic serum for the treatment of scarlet fever", Bull. John Hopkins Hosp. 36:134-171 (1925). Black, C.M. et al., "Detection of Streptococcal Pyrogenic Exotoxin Genes by a Nested Polymerase Chain Reaction", Molecular and Cellular Probes, Vol. 7, pp. 255-259 (1993). Bohach et al., "Staphylcoccal and Streptococcal Pyrogenic Toxins Involved in Toxic Shock Syndrome and Related Illnesses", Crit. Rev. Microbiol. 17:251-272 (1989). Bowie, J. et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions", Science 247:1306-1310

|   | DATE CONSIDERED   |
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| EXAMINER  |   |
| EXAMPLE Initial if reference considered, whether or not citation is in confor | mance with MPEP 609; draw line through citation if not in conformance and not |
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Date Mailed: October 22, 2003 Sheet 2 of 3

|                   | ORMATION DISCLOSURE STATEMENT     | Docket Number:<br>600.311USD1 | Application Number: 10/625,221 |  |
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| IN AN APPLICATION |                                   | Applicant: SCHLIEVERT ET AL.  |                                |  |
| Ci an             | (Use several sheets if necessary) | Filing Date: July 22, 2003    | Group Art Unit: 1645           |  |

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Sheet 3 of 3

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Name: Mark T. Skoog Reg. No.: 40,178

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